

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE: NAVIDEA BIOPHARMACEUTICALS
LITIGATION

Case No: 1:19-cv-01578-VEC

ECF Case

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF/COUNTERCLAIM-
DEFENDANT NAVIDEA BIOPHARMACEUTICALS, INC.'S AND
THIRD-PARTY DEFENDANT MACROPHAGE THERAPEUTICS, INC.'S
MOTION TO EXCLUDE EXPERT TESTIMONY OF TERRY L. ORR**

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Plaintiff/Counterclaim Defendant Navidea Biopharmaceuticals, Inc. (“Navidea”) and Third-Party Defendant Macrophage Therapeutics, Inc. (“Macrophage” or “MT”) submit this memorandum of law in support of their motion to exclude the expert testimony of Terry L. Orr (“Orr”), who submitted an expert report (the “Orr Report”) on behalf of Defendant/Counterclaim Plaintiff/Third-Party Plaintiff Michael M. Goldberg, M.D. (“Goldberg”).

PRELIMINARY STATEMENT

In an attempt to prove up damages, Goldberg has submitted the Orr Report in which he issues several opinions regarding an August 14, 2018 agreement entered into between Navidea and Goldberg (the “August Agreement”) that is the subject of Goldberg’s breach of contract claim. Specifically, the Orr report focuses on two provisions of the August Agreement, which provides that upon the happening of certain events,¹ (1) “Navidea will issue to Goldberg 23.5 million shares of Navidea common stock . . . under Regulation D of the Securities Act of 1933,” and (2) Navidea’s subsidiary, Macrophage, “will issue to Goldberg shares of MT Super Voting Common Stock in a number equal to 5.0% of the outstanding shares of MT.”

The Orr Report, however, goes well beyond the bounds of admissible expert testimony and does not contain any admissible opinion on damages. In fact, only one of Orr’s five opinions even expresses a damages number at all. Orr opines on issues on which he is not qualified, he proffers legal opinions that usurp the role of the Court, and he bases his damage calculations on methodologies he invented solely for this case. As a result, his methodologies are inherently unreliable, unproven and untested – and by extension, inadmissible.

¹ Navidea does not address herein whether these events occurred, or any other factual matter concerning liability, as that is a question of fact to be decided by the Court. Navidea will address only whether Orr’s opinions and testimony are admissible.

Orr's first two opinions concern the (1) the legal standards and requirements of Regulation D, Rule 144, and Form S-8, and the legal interpretation of the August Agreement, and (2) whether Navidea breached the August Agreement by failing to issue certain shares of stock to Goldberg. Orr does not have the expertise, qualifications, or experience to opine on these issues. Orr is an accountant who spent his entire career in the field of public accounting. Orr is not a lawyer, a regulator, or a stock transfer agent. He simply does not meet the evidentiary standard under Fed. R. Evid. 702 to qualify as an expert to opine on these issues. Even if Orr were qualified, his testimony and opinions still should be excluded because they are inadmissible legal opinions that improperly usurp the role of the Court and/or jury.

Orr's third opinion about what Navidea *intended* to do concerning a reverse stock-split is an inadmissible legal or factual conclusion, and an inadmissible opinion concerning Navidea's state of mind.

Orr's fourth and fifth opinions on damages (which are the only possible opinions for which he may possess qualifications to render) are inadmissible for numerous reasons. As demonstrated below, Orr used three different methodologies, each of which is based on conjecture, speculation and faulty assumptions. Two of his methodologies admittedly have not been peer reviewed, published, or generally accepted. The third methodology, arguably an accepted one, fails to incorporate reliable data and suffers from Orr's misapplication of the facts and methods to the case at hand. Orr's so-called methodologies simply fail to meet the level of intellectual rigor that characterizes the practice of an expert in the relevant field, and thus his damage opinions and testimony concerning Navidea and Macrophage stock should be excluded.

In short, there is nothing about Orr’s opinions that is proper or that assists the trier of fact. Consequently, the Court’s gatekeeping function requires that Orr’s unreliable and non-relevant expert opinions and testimony be excluded.

STATEMENT OF RELEVANT FACTS

Navidea filed a Complaint against Goldberg for breach of contract, breach of the covenant of good faith and fair dealing, declaratory judgment, and for breach of fiduciary duty. (*See* FAC.)² Goldberg is a former employee of Navidea and Macrophage. (FAC ¶¶ 3, 10.) He also served as the CEO of Navidea, the CEO of Macrophage, and a director of Macrophage. (FAC ¶ 3.)

I. The August Agreement

Navidea and Goldberg entered into the August Agreement on August 14, 2018. (FAC ¶ 12.) As relevant to this motion, the August Agreement provides that: (1) upon the occurrence of certain events and subject to certain sales and escrow restrictions, Navidea would issue Goldberg 23.5 million shares of Navidea stock under Regulation D; and (2) “MT will issue to Goldberg shares of MT Super Voting Common Stock in a number equal to 5.0% of the outstanding shares of MT.” (Declaration of Barry Kazan (“Kazan Decl.”) Ex. 1.); *see also* FAC ¶¶ 16-17.)

On November 22, 2018, Navidea issued Goldberg 18.5 million shares of Navidea stock – 13.5 million shares directly to Goldberg and the remaining 5 million shares to be held in escrow. (FAC ¶ 31.) Goldberg has not been able to sell any of these shares because they contain restrictive stock legends and Navidea has not provided written consent for the sale to occur. Navidea has not yet issued the additional 5 million shares to escrow. (FAC ¶ 32.) Although Goldberg was the CEO of Macrophage from August 14, 2018 through February 20, 2019, Goldberg never caused Macrophage to issue the Macrophage stock contemplated under the August Agreement.

² Navidea filed its first amended complaint (“FAC”) on April 26, 2019. [Dkt. No. 15.]

II. The Orr Report

Orr issued his report on September 30, 2021. (Kazan Decl. Ex. 2 (Orr Report).) Orr states that he was retained to:

- (1) Educate finder of fact with respect to attributes of shares issued pursuant to Reg D.
- (2) To opine on whether the Navidea shares purportedly issued to Dr. Goldberg were issued consistent with those standards.
- (3) Evaluate the damages sustained by Dr. Goldberg resulting from the breach.

(*Id.* Ex. 2 at 1-2.)

A. Orr's Stated Expertise, Qualifications And Expertise

Orr described his expertise, qualifications and experience, as follows:

I am a Partner with HKA [Inc.] in the Dallas office of the Forensic Accounting and Commercial Damages practice. I am a Certified Public Accountant licensed in the State of Texas with over 35 years of experience in the field of public accounting. I am a member of the American Institute of Certified Public Accountants ("AICPA"). I am also a Chartered Global Management Accountant ("CGMA"), a Certified Internal Controls Auditor ("CICA"), a Certified Construction Auditor ("CCA") and I am a member of the AICPA's Forensic & Valuation Services Section (FVS Section). My educational background includes a Bachelor of Science in Accountancy and Business Administration from Brigham Young University. I spent the first 27 years of my career conducting audits and reviews for companies in a variety of industries, including public and Regulation D filings. Subsequently, I have focused on providing litigation consulting services in forensic accounting matters, corporate investigations, fraud examinations, and damage computations.

(*Id.* at 1.)

B. Orr's First Two Opinions Concern The Legal Interpretation And Application Of Regulation D, Rule 144, Form S-8, And The August Agreement

Orr devotes significant portions of his report (at least 10 pages) to discussing and opining on the legal requirements of Regulation D, Rule 144, Form S-8 and the August Agreement,

including whether the stock legends on the stock issued to Goldberg were “authorized” or “required” by Regulation D or Form S-8. (*Id.* at 4-13 (Section II.B – II.D).) Orr’s legal assertions and conclusions include, but are not limited to, the following: (1) the requirements of Rule 504 of Regulation D and its “exemption from the registration requirements of the federal securities laws” (*Id.* at 4); (2) “the applicable conditions set forth in Rule 144” to “sell restricted or control securities to the public” (*Id.* at 6); (3) the requirements and limitations of a “restrictive [stock] legend,” including its application to Rule 144 and the “authority” of a “transfer agent” to “remove a restrictive [stock] legend” (*Id.* at 7-8); (4) whether Goldberg “qualif[ies] as a control person of Navidea” under the August Agreement (*Id.* at 10); (5) that a restrictive stock “legend indicates that the securities may not be resold in the marketplace unless they are registered with the SEC or are exempt from the registration requirements” (*Id.*); (6) that language in the Navidea stock legend is “***not authorized*** or required by Reg. D” (*Id.* at 11, 12, 16, 20) (emphasis added); and (7) that the stock “legend is ***not authorized*** or required for Form S-8 or shares issued in accordance with Form S-8 (or shares issued under Regulation D) and the language of the legend differs from the lock-up language contained in the August 14th Agreement and are ***not authorized*** or required by Regulation D” (*Id.* at 13) (emphasis added).

Orr then distills the above into the following two summary opinions:

1. The escrow and lockup legend placed on the shares issued by Navidea under the August 14th Agreement ***are not authorized or required under Regulation D or authorized by the terms of the August 14th Agreement***, and therefore the shares bearing those legends ***are not issued in accordance with Regulation D***.
2. Navidea ***failed to issue shares*** due to Dr. Goldberg on January 2, 2019, ***under the terms of the August 14th Agreement***.

(*Id.* at 23 (emphasis added).)

When Orr was questioned at his deposition, Orr stated that the term “not authorized” was a “poor term,” and that neither Regulation D nor Form S-8 prohibited Navidea from using the language it did in the stocks’ legends. (*Id.* Ex. 3 (Orr Tr.) at 61:21-62:10; 70:17-20.)

Orr also opined in his report that Navidea breached the August Agreement (*Id.* Ex. 2 at 2), and that “Dr. Goldberg did not receive the benefit of the bargain for which he bargained and has suffered financial harm and damage” (*Id.* at 20).

C. Orr’s Third Opinion Concerns Navidea’s Intention To Initiate A Reverse Stock Split

On page 13 of his report, Orr states that Navidea executed a 1 for 20 reverse stock split on April 26, 2019. Orr opines: (1) that Navidea intended to do a stock split when the August Agreement was signed seven months earlier; (2) that the August Agreement “does not contain language common for addressing the potential of a stock split or divide” and on the potential implications from the absence of such language; and (3) on why companies engage in reverse stock splits. (*Id.* at 14-15.) Orr then proffers his third summary opinion: “When [the August] agreement was executed, Navidea intended to initiate [a] reverse split of stock.” (*Id.* at 24.) At his deposition, Orr stated that this was not an “opinion,” but “a statement of fact.” (*Id.* Ex. 3 at 80:1-5.)

D. Orr’s Fourth Opinion Concerns Alleged Damages Relating To Navidea Stock And Uses Two Different And Inconsistent Methodologies

Orr created and used, solely for purposes of this litigation, two entirely different and inadmissible methodologies to assess Goldberg’s alleged damages for the Navidea shares. Orr uses one methodology (the “pre-split” methodology) to assess damages if the stock had not reverse-split. He then uses a completely different methodology (the “savvy investor” methodology) to assess damages if the stock had reverse-split.

i. *Orr's Pre-Split Methodology is Not Published, Peer Reviewed or Generally Accepted and Does Not Include a Valuation of Any Alleged Damages*

Orr's "pre-split" methodology does not provide a damage value. Instead, it purportedly provides a way to calculate damages after a trial has concluded. It is thus unclear how a judge or jury could use this methodology to actually determine a damage value prior to verdict. The methodology starts with an unknown, speculative future closing share price of Navidea "on the date before [] judgment is rendered" against Navidea, and ends with multiplying some unknown amount of shares by that unknown future share price. (*Id.* Ex. 2 at 17.)

Orr admitted at deposition that his "pre-split" methodology was contrived solely for the purpose of this litigation and developed based on his own "experience." (*Id.* at 16.) Orr also admitted that: (1) he had no knowledge of his methodology ever being used before; (2) he has never used the methodology before; (3) it is not a generally accepted methodology; (4) it has never been published; and (5) it has never been peer reviewed (except that his colleague at HKA, David Duffus, read over his report before it was issued).³ Orr testified as follows in response to counsel's questions:

Q. And have you written about this [pre-split] methodology anywhere?

A. No.

Q. Have you read about this methodology anywhere?

A. No.

Q. Has it been peer reviewed by anybody?

A. Yes.

Q. Who has it been peer reviewed by?

A. David Duffus.

Q. When you say David Duffus peer reviewed it, you mean he read your report?

A. He read through the second part of the review, yes.

Q. Other than David Duffus, has it been peer reviewed?

A. No.

³ Notably, Orr testified as to his own *inexperience* with valuations, admitting in deposition that he has never: (a) "published in the area of valuation"; (b) "written any articles"; (c) "taught any classes"; or (d) "edited any journals that deal with valuation." (Kazan Decl. Ex. 3 at 16:7-14.)

Q. Has this methodology been used by you before?

A. No.

Q. So other than the methodology that you've described here, there's no place to read about this as being an accepted methodology for valuation of pre-split shares?

A. No, not -- no. I don't think this issue would be very common, but, you know, the answer is no.

* * *

Q. Is this a methodology that's published anywhere?

A. No.

(*Id.* Ex. 3 at 84:15-85:13; 102:24-103:1.)

In assessing damages under his pre-split methodology, Orr does not use any regression analysis to account for various variables (including, but not limited to, trading volume, market cap, risk free rate, or share price). *Cf.* Expert Rebuttal Report of William Murray (the "Murray Report") (*Id.* Ex. 4 (Murray Report) at 10.).⁴ In addition, despite acknowledging Navidea's historically low trading volume on page 23 of his report (generally below 2 million shares per day before the reverse stock split), and the unusually large amount of new Navidea shares (23.5 million shares), Orr did not address, consider or opine on whether a "blockage discount"⁵ should be applied, which would result in a lower share price from the sudden oversupply of Navidea shares if all shares were sold at once. *Cf.* Murray Report (*Id.* at 12.) Rather, Orr simply assumed that all shares could be sold at once and at the highest stock price. (*Id.* Ex. 3 at 113:8 – 114:15 ("I didn't look at volume

⁴ A "[m]ultiple regression analysis is a statistical tool for understanding the relationship between two or more variables. Multiple regression involves a variable to be explained—called the dependent variable—and additional explanatory variables that are thought to produce or be associated with changes in the dependent variable. . . . Multiple regression analysis is sometimes well suited to the analysis of data about competing theories in which there are several possible explanations for the relationship among a number of explanatory variables." *See CCM Rochester, Inc. v. Federated Invs., Inc.*, Case No. 14-cv-3600, 2016 WL 11617452, at fn. 9 (S.D.N.Y. Aug. 31, 2016).

⁵ A blockage discount is "an amount or percentage deducted from the current market price of a publicly traded stock to reflect the decrease in the per share value of a block of stock that is of a size that could not be sold in a reasonable period of time given normal trading volume." International Glossary of Business Valuation Terms (*available at* <https://www.nacva.com/content.asp?contentid=166>); *see also Janis v. Comm'r*, 469 F.3d 256, 258 (2d Cir. 2006) ("The theory behind a blockage discount . . . is that if a large quantity of any item is added to the existing supply, the price of all such items will tend to fall.")

trades. I just said the shares were at this value on that date. The shares, if they had been and could have been traded on that date at that volume, this would have been the amount they would have been worth.”.)

ii. *Orr’s Savvy-Investor Methodology is Not Published, Peer Reviewed or Generally Accepted and is Based on Goldberg’s Ability to Time the Stock Market Perfectly to Sell at the Highest Share Price*

Orr’s “savvy investor” methodology presumes that because Goldberg is a “savvy investor,” (something Orr possesses no qualifications to determine), Goldberg would have had the foresight and ability to perfectly time the stock market to sell his Navidea stock at the height of its stock price. Orr opined that:

[Goldberg] would have expected [the Navidea] share price to increase and sustain at a higher price after an announcement that triggers that volume increase, therefore it is reasonable to assume Dr. Goldberg could have taken advantage of this higher share price and sold his shares for the higher end of the range of damages presented above, resulting in a value of \$5,675,250 (weighted average of $\$4.83 \times 1,175,000 = \$5,675,250$).

(*Id.* Ex. 2 at 23.)

To calculate the alleged damages for this methodology, Orr selected the following three dates: (1) “the earliest possible date”; (2) “the date of the highest stock price for the which the Shares could have been sold [August 3, 2020]”; and (3) September 28, 2021, two days before Orr’s expert report was issued. (*Id.* at 21.) For the “earliest possible date,” Orr assessed the requirements of Regulation D and the language in the stock legends, and opined that the earliest possible sale dates for each of the three separate tranches of stock were May 21, 2019, May 15, 2020 and June 25, 2020, respectively. (*Id.* at 17-18.) Orr then multiplied the number of shares in each lot of stock by the historical share price on the specified date, (*Id.* at 21-22), and summarized those alleged damages as follows:

Table 3: Range of Shares Value

Transfer	Post Split Shares	Sold at Earliest	Sold at High	Sold Today	Min	Max
1	675,000	\$ 965,250	\$ 3,341,250	\$ 1,134,000	\$ 965,250	\$ 3,341,250
2	250,000	275,000	1,237,500	420,000	275,000	1,237,500
3	250,000	997,500	1,237,500	420,000	420,000	1,237,500
	1,175,000	\$ 2,237,750	\$ 5,816,250	\$ 1,974,000	\$ 1,974,000	\$ 5,816,250

But Orr immediately abandoned the “earliest possible date” and the date prior to his expert report for purposes of his ultimate opinion, and concluded that Goldberg’s expertise as a savvy investor could lead to only one damage conclusion – that Goldberg would sell the Navidea stock at its peak stock price. Orr then used a “weighted average” price of the shares between July 20, 2020 to August 7, 2020, when the stock was trading at its highest price, and concluded that “Dr. Goldberg was damaged in the amount of \$5,675,250.” (*Id.* at 23.) Orr opines, without basis, that the rise in the stock price during that time was due to an 8-K issued by Navidea two months prior (May 21, 2020) and Goldberg would have been able to time the market based on that 8-K knowing the price would peak two months later. (*Id.*).

Even accepting a “savvy investor” theory, Orr testified that he did not actually ask Goldberg about his trading history with Navidea stock. When confronted with this fact, he suggested that this information was not available to him – even though his entire theory was premised on his discussions with Goldberg. (*Id.* Ex. 3 at 33:9-21; 110:25-112:8.)

Orr also testified that his “savvy investor” methodology: (1) had never been used before; (2) was not in any treatise; (3) was not an accepted methodology; (4) had never been published, and (5) had never been peer reviewed (except that his colleague at HKA, David Duffus, read over his report before he finalized and issued it).

Q. There’s no treatise you’re aware of that applies this model that you’ve come up with?

A. No.

MR. ZIMMER: Objection.

Q. And there's no -- you have never published this model, correct?

MR. ZIMMER: Objection.

A. No.

Q. And it's not been peer reviewed other than Mr. -- I've forgot his name already. Other than the person who works with you?

MR. ZIMMER: Objection.

A. Yes.

(*Id.* at 117:8-20.) As with his other methodologies, Orr again failed to use any regression analysis or consider the effect of a “blockage discount.”

E. Orr's Fifth Opinion On Macrophage Stock Damages Does Not Assess A Damage Value

Orr's final opinion is that “Dr. Goldberg was damaged by Navidea's failure to issue the MT Super Voting Shares to Dr. Goldberg.” (*Id.* Ex. 2 at 24.) Orr does not calculate any damage value, he simply concludes that Goldberg was damaged.

For the damage assessment, Orr uses a *third* methodology, referred to herein as the “vague-interest” methodology. Orr bases his methodology on a vague expression of interest that two potential investors had in Macrophage, which investment never transpired, and not on any true transaction comparisons or a completed investment. Because he had no reliable data points, Orr provides a range of values for what Goldberg's 5% common share interest in Macrophage could be if one of two preliminary “investment offers” for “an unknown share of” Macrophage (one \$10 million and the other \$25 million) were finalized. But Orr does not know (1) the terms of any of the proposed deals – e.g., how much equity would be acquired, or (2) whether the equity to be acquired were preferred or common shares and most importantly how an investment might impact Goldberg's 5% holdings. And Orr readily admits neither of the “investment offers” were put in writing or reduced to term sheets, much less finalized. (*Id.* at 25 (“Ultimately, there was no investment in MT”).) At his deposition, Orr also admitted that he “didn't do a full analysis of the value of Macrophage. I just showed in my report that there was value in Macrophage. . . .” (*Id.*

Ex. 3 at 43:8-13.) Orr also, admitted there was no publication or treatise supporting this “vague-interest” methodology (*id.* at 127:24-128:14), and he never addressed the wildly different investment offers, one 2.5x the other. In fact, Orr does not even bother to do the math on what the value of a \$10 million investment would look like as a damages theory, instead choosing the \$25 million investment presumably because that rendered a higher value for Goldberg. (*Id.* Ex. 2 at 24-25.)

ARGUMENT

I. Legal Standard

A. Choice Of Law

The August Agreement states that it “shall be governed by and construed in accordance with the laws of the State of Delaware without regard to its conflicts-of-law provisions.” (*Id.* Ex. 1.) But the parties agreed that any action to enforce the August Agreement was to be exclusively venued in New York. (*Id.*) Because the matter is venued in New York, the admissibility of expert testimony is governed under the law of this Circuit. *Astra Aktiebolag v. Andrx Pharms., Inc.*, 222 F. Supp. 2d 423, 486 (S.D.N.Y. 2002) (“evidentiary rulings concerning the admissibility of expert testimony are generally governed by regional circuit law”); *In re Omeprazole Pat. Litig.*, 490 F. Supp. 2d 381, 400 (S.D.N.Y. 2007) (same).

B. Admissibility Of Expert Testimony

Federal Rule of Evidence 702 governs the admissibility of expert testimony. A proposed expert witness must be “qualified as an expert by knowledge, skill, experience, training, or education.” Fed. R. Evid. 702. Once qualified, the expert may offer opinion testimony if:

(a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;

(b) the testimony is based on sufficient facts or data;

(c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 tracks the Supreme Court’s holding in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) and its progeny. *See* Fed. R. Evid. 702 advisory committee’s note; *see also Roman v. Sprint Nextel Corp.*, Case No. 12-cv-276, 2014 WL 5026093, at *3 (S.D.N.Y. Sept. 29, 2014).

“The district court acts as a gatekeeper against unreliable expert testimony.” *El Ansari v. Graham*, Case No. 17-cv-3963, 2019 WL 3526714, at *3 (S.D.N.Y. Aug. 2, 2019) (*citing United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)). The gate-keeping role is to “make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.” *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). “[T]he district court should undertake a *rigorous examination* of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand.” *In re Mirena IUS Levonorgestrel-Related Prod. Liab. Litig. (No. II)*, 982 F.3d 113, 123 (2d Cir. 2020) (emphasis in original).

The threshold question for admissibility is whether the “proffered expert testimony is relevant.” *Amorgianos v. Nat. R.R. Passenger Corp.*, 303 F.3d 256, 265 (2d Cir. 2002). An expert opinion is relevant if it has “fit,” meaning the “expert testimony . . . is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute.” *Daubert*, 509 U.S. at 591. Expert testimony is irrelevant and lacking in “probative value” when it is based on fundamental errors and faulty assumptions. *Raskin v. Wyatt Co.*, 125 F.3d 55, 67-68 (2d Cir. 1997).

If the expert opinion is relevant, the Court must then determine “whether the proffered testimony has a sufficiently reliable foundation to permit it to be considered.” *Amorgianos*, 303 F.3d at 265. *Daubert* sets forth several factors of reliability, including: (1) “whether a theory or technique . . . can be (and has been) tested”; (2) “whether the theory or technique has been subjected to peer review and publication”; (3) whether uniform “standards controlling the technique’s operation” exist; and (4) whether the theory or technique enjoys “general acceptance” within an identifiable relevant scientific or professional community. *Daubert*, 509 U.S. at 593-94. While the inquiry under Rule 702 is a “flexible” one, “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert.” *Amorgianos*, 303 F.3d at 266 (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). Thus, “when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* and Rule 702 mandate the exclusion of that unreliable opinion testimony.” *Amorgianos*, 303 F.3d at 266 (emphasis added). Similarly, expert testimony should be excluded “if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith” *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996) (internal citations omitted).

Expert testimony also is not admissible if it usurps the role of the judge or jury. *United States v. Lumpkin*, 192 F.3d 280, 289 (2d Cir. 1999) (expert testimony is inadmissible “if it will usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it”). Thus, an expert witness “may not present testimony in the form of legal conclusions.” *Cameron v. City of New York*, 598 F.3d 50, 62 (2d Cir. 2010). While “an expert may opine on an issue of fact within the jury’s province, he may not

give testimony stating ultimate legal conclusions based on those facts.” *United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991). Courts thus exclude expert testimony that “provide legal opinions, legal conclusions, or interpret legal terms; those roles fall solely within the province of the court.” *Scott v. Chipotle Mexican Grill*, 315 F.R.D. 33, 48 (S.D.N.Y. 2016) (*quoting Highland Capital Mgmt. L.P. v. Schneider*, 379 F.Supp.2d 461, 470 (S.D.N.Y. 2005)). Similarly, no expert may “supplant the role of counsel in making argument at trial, and the role of the jury [in] interpreting the evidence.” *Primavera Familienstiftung v. Askin*, 130 F.Supp.2d 450, 529 (S.D.N.Y. 2001) (*abrogated on other grounds by Casey v. Merck & Co.*, 653 F.3d 95 (2d Cir. 2011)).

The “proffering party bears the burden of establishing admissibility under Rule 702 by showing that: (1) the expert is qualified; (2) the proposed opinion is based on reliable data and methodology; and (3) the proposed testimony would be helpful to the trier of fact.” *El Ansari*, 2019 WL 3526714, at *3 (S.D.N.Y. Aug. 2, 2019) (*citing Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005)). Here, Goldberg and Orr have failed to meet this burden.

II. The Court Should Exclude The Expert Testimony Of Orr

Orr’s expert opinions and testimony should be excluded on multiple grounds. *First*, he is not qualified as an expert to render opinions on federal securities laws or the interpretation of legal agreements. *Second*, Orr’s opinions on those issues are inadmissible legal opinions. *Third*, Orr’s damage analyses use unreliable methodologies, speculation, and faulty assumptions, and are thus of no use or relevance to the judge or jury.

A. Orr’s Opinions And Testimony On Regulation D, Rule 144, Form S-8 And The August Agreement Should Be Excluded Because Orr Is Not Qualified As An Expert In Those Matters

Orr is not qualified as an expert under Fed. R. Evid. 702 to offer his first two opinions – on Regulation D, Rule 144, Form S-8, and the August Agreement, or whether Navidea issued stock in compliance with any of the foregoing. As such, his opinions and testimony on such matters

should be excluded. *Fin. Guar. Ins. Co. v. Putnam Advisory Co., LLC*, Case No. 12-cv-7372, 2020 WL 4251229, at *4 (S.D.N.Y. Feb. 19, 2020) (finding expert not qualified to render opinion “on what attachment point the rating agencies would have calculated if they had received the final Pyxis portfolio” because, among other reasons, the expert “never worked at a rating agency”); *see also 523 IP LLC v. CureMD.Com*, 48 F. Supp. 3d 600, 647 (S.D.N.Y. 2014) (“based on his education and experience,” expert was “not qualified to testify . . . in the fields of computer programming, systems analysis or engineering, applications expertise, or software engineering”); *Malletier v. Dooney & Bourke, Inc.*, 525 F. Supp. 2d 558, 642 (S.D.N.Y. 2007) (“Testimony on subject matters unrelated to the witness’s area of expertise is prohibited by Rule 702.”)

Orr is an accountant and has spent his entire career in the accounting profession, with most of that time spent being as an auditor. (Kazan Decl. Ex. 2 at 1 and Appendix 1 (CV)). By his own admission, Orr’s experience with Regulation D is limited to auditing and reviewing the financial statements of public companies, for which some were “involved in IPO and Reg. D offerings.” (*Id.*) Orr is not an attorney, an SEC regulator, or a stock transfer agent. He does not specialize in regulatory filings or securities litigation. Orr does not claim to have ever worked for the SEC or have any experience with Regulation D, Rule 144 of Form S-8 from a compliance perspective, nor does he claim to have any experience as an executive of a company (public or otherwise) that issues restricted stock. Orr also does not claim to have any experience advising his clients on restricted stock legends or their compliance with legal standards. (*Id.*)

While Orr has several professional accounting and auditing certifications (CGMA, CICA, CCA) and is a member of various accounting and valuation groups (AICPA and FVS), none has any bearing on the knowledge, experience or expertise required to proffer opinions on the interpretation of and compliance with federal securities laws or contracts. The fact that Orr may

be qualified as an expert in certain accounting or valuation matters, does not mean Orr may testify on another aspect in which he is not qualified. *Arista Recs. LLC v. Lime Grp. LLC*, Case No. 06-cv-5936, 2011 WL 1674796, at *2 (S.D.N.Y. May 2, 2011) (“[A]n expert who is qualified in one field cannot offer an opinion about aspects of the case in another field for which she is not qualified.”); *Malletier*, 525 F.Supp.2d at 642 (“An expert qualified in one subject matter does not thereby become an expert for all purposes.”).

Accordingly, all of Orr’s opinions concerning legal requirements and interpretations of Regulation D, Rule 144, Form S-8 and the August Agreement should be excluded because Orr is not qualified to opine on these matters.

B. Orr’s Opinions And Testimony On Regulation D, Rule 144, Form S-8 And The August Agreement Also Should Be Excluded Because They Are Inadmissible Legal Opinions

If the Court determines that Orr is qualified to opine on Regulation D, Rule 144, Form S-8 and compliance with the August Agreement, his testimony and opinions about those issues still should be excluded because he is improperly proffering legal opinions and usurping the role of the judge and jury. *Lumpkin*, 192 F.3d at 289 (expert testimony is inadmissible “if it will usurp either the role of the trial judge in instructing the jury as to the applicable law or the role of the jury in applying that law to the facts before it”) (internal quotations omitted); *Scott*, 315 F.R.D. at 48 (“Courts exclude expert testimony that ‘provide[s] legal opinions, legal conclusions, or interpret[s] legal terms; those roles fall solely within the province of the court’”) (*quoting Highland Capital Mgmt. L.P. v. Schneider*, 379 F.Supp.2d 461, 470 (S.D.N.Y. 2005)).

Goldberg cannot refute that Orr’s first two opinions are purely legal opinions. The first page of Orr’s report states that two of his objectives are to “Educate finder of fact with respect to attributes of shares issued pursuant to Reg D,” and “opine on whether the Navidea shares purportedly issued to Dr. Goldberg were issued consistent with those standards.” (Kazan Decl. Ex.

2 at 1.) Orr then proceeds to do exactly that – opining on: (1) the meaning and interpretation of Regulation D, Rule 144 and Form S-8; (2) the propriety of the stock legends; (3) the requirements in selling restricted securities; (4) the definition of a control person and whether Goldberg qualifies as a control person; (5) whether Navidea complied with the requirements of Regulation D, Rule 144 and Form S-8; and (6) whether Navidea complied with or breached the terms of the August Agreement. Each is an inadmissible legal opinion.

C. Orr’s Opinions And Testimony Concerning What Navidea *Intended* To Do Concerning A Stock Split Should Be Excluded Because It Is An Inadmissible Legal Conclusion

Orr’s third opinion concerns Navidea’s intentions or “state of mind.” Orr opines that “When [the August] agreement was executed, Navidea *intended* to initiate a reverse stock split.” (Emphasis added.) This opinion on Navidea’s intentions or state of mind is not admissible. *Board of Trustees of AFTRA Retirement Fund v. JPMorgan Chase Bank N.A.*, Case No. 09-cv-686, 2011 WL 6288415 at *8 (S.D.N.Y. Dec. 15, 2011) (“There is no dispute that opinions concerning state of mind are an inappropriate topic for expert opinion.”). This opinion also is inadmissible because it is an ultimate conclusion of law for the judge or jury to make. *Lumpkin*, 192 F.3d at 289 (excluding expert testimony where expert usurped the role of the jury). Similarly, Orr’s opinions on pages 14-15 of his report concerning “language” commonly included in stock legends also is inadmissible because he is not qualified as an expert to testify on these issues. Orr is not a lawyer, a regulator, or a stock transfer agent. Nor does Orr claim to have any relevant professional experience that demonstrates he is qualified to opine on what language should be included in stock legends. Accordingly, Orr’s opinions on Navidea’s intentions or language expected to be in, or language common to, stock legends is inadmissible.

D. Orr's Damage Opinions And Testimony On Navidea Stock Should Be Excluded Because The Methodologies Used To Calculate Damages Are Not Reliable And The Conclusions Are Not Relevant

Orr's damage opinions and testimony relating to the Navidea stock should be excluded because they cannot meet the relevance or reliability thresholds of Fed. R. Evid. 702. Orr uses two different and inconsistent methodologies to value damages for the Navidea stock – the “pre-split” methodology and the “savvy investor” methodology. Each is based on unreliable principles and methods, speculation, and faulty assumptions and each are of no relevance to a judge or jury.

i. Orr's Damage Opinions and Testimony Using the “Pre-Split” Methodology Should be Excluded

As an initial matter the “pre-split” methodology cannot satisfy the relevance threshold because it does not provide an actual damage value. Rather, it suggests how damages could be calculated after a trial has concluded. This is not useful or relevant to the Court as it cannot assist the trier of fact to determine a damage value. *Boucher*, 73 F.3d at 21 (“expert testimony should be excluded if it is speculative or conjectural”); *Raskin*, 125 F.3d at 67 (affirming exclusion of expert opinion because it lacked “probative value”); *CCM Rochester*, 2016 WL 11617452, at *7 (excluding expert testimony because it “lack[ed] any meaningful [] analysis to assist the finder of fact”).⁶

Even if the “pre-split” methodology could get past the relevance threshold, Orr's damage opinion should be excluded because it fails to satisfy the reliability threshold under *Daubert*. The methodology (1) has not been tested, (2) has not been subject to peer review or publication, and (3) is not generally accepted. While the test for reliability is “flexible” and does not require strict

⁶ Furthermore, if Orr's statement that “Navidea intended to initiate a reverse split of stock” was a statement of fact as he testified (Kazan Decl. Ex. 3 at 80:1-5.), that entirely undercuts the relevance of the “pre-split” methodology. If true, there would be no basis to assert Goldberg's shares should be valued without the reverse 1 for 20 stock split because everyone had the same knowledge, and intended, that the shares would be subject to the reverse stock split.

adherence to the enumerated *Daubert* criteria, the methodology cannot be so inadequate as to fail to support the conclusion reached. *Amorgianos*, 303 F.3d at 266. If it is so inadequate, “*Daubert* and Rule 702 *mandate the exclusion* of that unreliable opinion testimony.” *Id.*

Orr’s testimony and opinions on damages are precisely the scenario for which *Daubert* and Rule 702 mandate exclusion. His conclusions rely on speculative future stock prices and the speculative rendering of a future judgment. His valuation methodology contravenes *Duncan v. Theratx, Inc.*, 775 A.2d 1019, 1022 (Del. 2001), where the Delaware Supreme Court specifically rejected a valuation methodology that assumed the stockholder would elect to “retain the shares” because the court would “not take into account [a] delay in the sale of [] shares for speculative purposes.” *Id.* at 1025, 1027.⁷

Similar to the flaws in his other methodologies, Orr fails to use any regression model to account for various variables. *CCM Rochester*, 2016 WL 11617452, at *4 (excluding expert opinion that failed to use a regression analysis because the expert report did “not employ the rigor one would expect from an expert in his field nor a reasoned manipulation of numbers”). Orr also fails to apply a “blockage discount” or even explain why such a discount should not be used. Instead, Orr assumed, without any explanation, that Goldberg could sell all the shares at once. *El Ansari*, 2019 WL 3526714, at *6 (“expert’s testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors”).

Because Orr’s damage opinion is based on speculative data, faulty assumptions, and an unreliable methodology, it should be excluded as “there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec.*, 522 U.S. at 146; *Amorgianos*, 303 F.3d

⁷ For substantive issues, such as damages, Delaware law applies because of the Delaware governing law provision in the August Agreement.

at 266 (exclusion of testimony is mandatory “when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached”); *Crescenta Valley Water District v. Exxon Mobile Corp.*, Case No. 07-cv-2630, 2013 WL 12120533, at *7 (S.D.N.Y. March 14, 2013) (“Any step that renders the analysis unreliable renders the expert’s testimony inadmissible.”).

ii. *Orr’s Damage Opinions and Testimony Using the “Savvy Investor” Methodology Should be Excluded*

Orr’s “savvy investor” methodology, and his damage opinion derived therefrom, suffers similar fatal flaws as his “pre-split” methodology. The “savvy investor” methodology does not meet the reliability threshold under *Daubert*, as it (1) has not been tested, (2) has not been subject to peer review or publication, and (3) is not generally accepted. And like the “pre-split” methodology, the “savvy investor” methodology is so inadequate that *Daubert* and Rule 702 mandate its exclusion. *Amorgianos*, 303 F.3d at 266.

Orr again failed to use any regression analysis and he failed to use or even consider the use of a blockage discount. Orr simply assumed that Goldberg would be able to time the market and sell all of his share at the highest stock price. *CCM Rochester*, 2016 WL 11617452, at *4 (the “expert opinion regarding asset allocation is not admissible because it does not employ the rigor one would expect from an expert in his field nor a reasoned manipulation of numbers”); *El Ansari*, 2019 WL 3526714, at *3 (“expert’s testimony must at least address obvious alternative causes and provide a reasonable explanation for dismissing specific alternate factors”).

The “savvy investor” methodology also contravenes *Duncan v. Theratx, Inc.*, 775 A.2d 1019, because a court cannot “take into account [a] delay in the sale of [] shares for speculative purposes” to conclude “that the stockholders would have sold at the highest possible share price during the period.” *Id.* at 1023, 1025; *see also Board of Trustees of AFTRA Retirement Fund*, 2011

WL 6288415, at *8 (“There is no dispute that opinions concerning state of mind are an inappropriate topic for expert opinion.”). The proposition expressly rejected in *Duncan* is precisely what Orr does here – he acknowledges that Goldberg could have started selling 675,000 shares on May 21, 2019, but was somehow “savvy” enough to hold those shares for another year until an 8-K was issued on May 21, 2020 and then hold the stock another 60 days before selling them to achieve the highest price. (Kazan Decl. Ex. 2 at 21, 25). Assuming Orr had a basis for this opinion – which does not appear in his report in the first instance – it would still be subject to exclusion under *Duncan*. And even if Orr could consider Goldberg’s trading prowess (which he cannot), Orr never even had a discussion with Goldberg about his trading history in Navidea’s stock.

Orr also fails to explain the different methodology approaches. Orr fails to explain why his “pre-split” methodology is based on a future unknown stock price whereas the “savvy investor” methodology is based on Goldberg’s purported stock-trading savvy. Orr’s different, inconsistent and flawed valuation methodologies are nothing more than inadmissible “*ipse dixit*.” *CCM Rochester*, 2016 WL 11617452, at *4; *Boucher*, 73 F.3d at 21 (a trial judge should exclude expert testimony “if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith”) (internal citations omitted). The “savvy investor” damage opinion thus should be excluded because “there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec.*, 522 U.S. at 146.

iii. Orr’s Damage Opinions are Specifically Rebutted by Navidea’s Expert

The Court also should consider the Expert Rebuttal Report of William Murray in assessing the inadmissibility of Orr’s opinions. The Murray Report further demonstrates Orr’s flawed “savvy investor” methodology and failure to apply or even consider a blockage discount. (Kazan Decl. Ex. 4.) Murray notes the “highly speculative” conclusion that Goldberg “would achieve near perfect market timing.” (*Id.* at 5-6.) He further notes that “Mr. Orr does not cite to any support for

his conclusion regarding the timing of sales and I am unaware of any empirical data or professional literature that suggests any person, much less Dr. Goldberg, can perfectly time the market to realize the maximum gains on publicly traded shares.” (*Id.* at 6.) Murray also addresses the significance and relevance of the “blockage discount,” and explains that it “should be applied” because “a sale [of all the Navidea stock] would almost certainly result in significant downward pressure on the [stock] price due to the sudden excess supply of Navidea common stock.” (*Id.* at 6-7.)

E. Orr’s Damage Opinions And Testimony On Macrophage Stock Should Be Excluded Because The Methodology Used To Calculate Damages Is Not Reliable And His Conclusions Are Not Relevant

Orr’s damage opinion concerning Macrophage uses yet another different methodology (the “vague-interest” methodology). In this methodology, Orr attempts to use a market comparison approach to value Macrophage but fails to incorporate any reliable data to adequately calculate a valuation, and then fails to provide a definitive damage opinion. No part of the Macrophage damage opinion is admissible.

First, because Orr does not provide any actual value of the damages, his damages opinion is not relevant to a judge or jury. *Raskin*, 125 F.3d at 65 (affirming exclusion of expert opinion as “irrelevant and inadmissible” where “the report was probative of no material fact”); *CCM Rochester*, 2016 WL 11617452, at *7 (excluding expert testimony because it “lack[ed] any meaningful [] analysis to assist the finder of fact”). *Second*, Orr’s opinion is based on speculation as to what the value of Macrophage may have been in connection with two potential investment offers, without knowing how many shares or the types of shares that would have been exchanged for either of the purported investments, and knowing that the investments never occurred. *Boucher*, 73 F.3d at 21 (“expert testimony should be excluded if it is speculative or conjectural”). *Third*, Orr admitted in deposition that he “didn’t do a full analysis of the value of Macrophage.” (Kazan Decl. Ex. 3 at 43:8-13.) Each of these faulty steps on their own render Orr’s opinions inadmissible.

Crescenta Valley, 2013 WL 12120533, at *7 (“Any step that renders the analysis unreliable renders the expert’s testimony inadmissible.”).

The Murray Report also undercuts Orr’s Macrophage analysis. Murray notes that Orr failed to apply a “comprehensive analysis of value using any of the three [accepted] approaches.” (Kazan Decl. Ex. 4 at 14.) Murray acknowledges that a company can be valued using a market comparison approach, but that Orr “has insufficient data” to use that approach. (*Id.*) Orr seems to agree. (Kazan Decl. Ex. 3 at 44:8-24).

Accordingly, Orr’s opinion concerning Macrophage should be excluded because it is speculative, and it is not relevant to a judge or jury as it lacks any conclusion of a damage value. *Boucher*, 73 F.3d at 21 (a trial judge should exclude expert testimony “if it is speculative or conjectural, or if it is based on assumptions that are so unrealistic and contradictory as to suggest bad faith”) (internal citations omitted); *Amorgianos*, 303 F.3d at 266 (the exclusion of testimony is mandatory “when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached”).

In the past, this Court expressed its skepticism of Goldberg’s approach when it wrote: “[t]his Court is left with the distinct impression that [the fee submissions] are based less on the reality on the work . . . than on their desire . . . to obtain the greatest possible awards for their client.” (Order on R&R at 4, Dkt. No. 198, adopted in full Dkt. No. 207). Navidea and Macrophage respectfully submit that this is precisely what Orr did and why his methodologies must be rejected and his opinions excluded.

CONCLUSION

Accordingly, for the reasons set forth herein, this Motion to Exclude the Expert Testimony of Terry L. Orr should be granted.

Date: February 4, 2022
New York, New York

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2022, I caused to be served on counsel of record, electronically via the Court's electronic filing system, a true and correct copy of **Plaintiff/Counterclaim-Defendant Navidea Biopharmaceuticals, Inc.'s and Third-Party Defendant Macrophage Therapeutics, Inc.'s Memorandum of Law in Support of Motion to Exclude the Expert Testimony of Terry L. Orr.**

/s/ Barry M. Kazan

Barry M. Kazan